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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/612,742 | 07/02/2003 | Donald Jackson | D0149 NP | 6699 |

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| EXAMINER | |
|---|---|
| GEBREYESUS, KAGNEW H | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1652 | |

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/612,742 | JACKSON ET AL. | |
| | Examiner | Art Unit | |
| | Kagnew H Gebreyesus | 1652 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *20 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 8, 9, 14-17 are drawn to DNA, vector host cells method of production of protein, classified in class 536, subclass 23.2.

II. Claims 5-6, 10 and 18 are drawn to human phosphatase polypeptides, classified in class 435, subclass 196.

III. Claims 11 and 20 in part are drawn to a treatment method using the phosphatase polypeptides, classified in class 424, subclass 94.6.

IV. Claims 11 and 20 in part are drawn to a treatment method using the phosphatase polypeptides modulator, classified in class 514 subclass 789.

V. Claims 12 and 19 are drawn to a method of diagnosing a pathological condition based on mutation on the DNA sequence encoding the protein phosphatase, classified in class 435, subclass 6.

VI. Claims 13 are drawn to a method of diagnosing a pathological condition based on the presence or expression of the protein phosphatase, classified in class 435 subclass 21

VII. Claim 21 is drawn to a method of screening for a phosphoprotein or a peptide binding partner to the protein phosphatase, classified in class 530 subclass 417.

VIII. Claim 22 is drawn to a computer designed to produce three-dimentional representation of a molecule or a molecular complex comprising the structural coordinates of the BMY_HPP13 model, classified in class 712, subclass 1.

IX. Claim 23 is drawn to a method for identifying a mutant with altered biological properties, function or activity of BMY_HPP13 classified in class 435, subclass 440.

X. Claim 24 is drawn to a method of designing or selecting for potential modulators of BMY_HPP13 classified in class 700, subclass 90.

XI. Claim 7 is drawn to an isolated antibody that binds specifically to the isolated polypeptide classified in 530 subclass 387.1

2. Inventions group I DNA, vector, host cells and invention in group II drawn to an isolated polypeptide and the antibody of group XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the DNA of group I and the protein of group II each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The DNA comprises a nucleic acid sequence and the protein group II comprise amino acid sequences. The DNA has other utilities besides encoding the protein such as hybridization probe, the proteins can be made by another method such as isolation from natural sources or chemical synthesis.

3. The DNA of Group I and the antibody of group XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as being capable of use together and they have different modes of operation, different function, or different effects (MPEP 806.04, MPEP 808.01). In the instant case the DNA in group I are separate and distinct from the antibodies in

group XI as they are physically and functionally distinct chemical entities. Accordingly restriction is appropriate.

4. Invention of group II phosphatase polypeptide and invention of group XI antibodies are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the phosphatase polypeptide of group II and the antibody of group XI each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The protein phosphatase has other utilities besides serving as an immunogen for the production of the antibody. For instance the protein can be used as a treatment agent.

5. Inventions in group I DNA and the treatment method of group III and IV, the diagnostic method of group VI, the screening method of group VII, the method of identifying a mutant of group IX and the method of designing modulators of BMY_HPP13 of group X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of groups III, IV, VI, VII, IX and X do not require the DNA of group I as they are neither used or made by any of groups III, IV, VI, VII, IX and X.

6. Inventions in group I and invention of group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the expressed protein can be used to diagnose the pathological condition.

7. Inventions II and group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein can be used as an immunogen to induce antibodies.

8. Inventions in group II phosphatase polypeptide and the treatment method of group IV, the diagnosing method of group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of treatment using the phosphatase polypeptides modulator of group IV does not require the phosphatase polypeptide of group II. Likewise the method of diagnosing a pathological condition based on the mutation on the DNA sequence or the amount encoding the phosphatase polypeptide does not require the phosphatase polypeptide.

9. Inventions group II and inventions of group VI, VII, IX and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the phosphatase polypeptide can be used as an immunogen to induce an antibody which is different from using it for the methods of groups VI and VII, IX and X.

10. Inventions XI and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the pathological condition can be diagnosed by the level of mRNA expression or by the activity of the polypeptide rather than the amount of polypeptide.

11. Inventions in group I, II and IX are unrelated to inventions of group VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case although the computer can be used to design a three-dimensional representation of the phosphatase polypeptide, it does not require the DNA of group I or phosphatase polypeptide of group II or the antibody of group XI.

12. Each one of methods in inventions of groups III, IV, V, VI, VII, IX and X are mutually exclusive and independent as they comprise different materials, and/or different steps and/or attain different objectives. For instance the material used in group III is a protein and the material used in group IV could be any chemical entity. The material and steps and objective in group V is based on the nucleic acid encoding the phosphatase polypeptide. The steps and objectives and/or material used in groups VI, VII and X are independent of each other and attain different objectives.

13. Inventions in groups III, IV, V, VI, VII, IX and X are unrelated to the inventions in group VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects

(MPEP § 806.04, MPEP § 808.01). In the instant case the computer based three-dimentional molecule design method of group VIII is unrelated to each one of the methods of groups III, IV, V, VI and VII, since the method of treatment method (groupsIII anf IV), the diagnostic methods (groups V and VI) or the screening method (group VII) do not require the invention of group VIII.

14. Inventions in group IX and X are related to invention in group VIII as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case identifying a mutant with altered biological activity (group IX) can be practiced by random mutagenesis techniques and selecting a compound as a potential modulator of BMP_HPP13 (group X) can be practiced using in vitro binding assay techniques.

15. The antibodies of group XI are unrelated to the treatment method of groups III and IV, the method of diagnosing of group V, the method of screening for a phosphoprotein of group VII, the method of identifying a mutant with altered biological activity of group IX or the method of designing or selecting for potential modulators of the polypeptide of group X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies of group XI are not required for the other groups.

1. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

2. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43).

3. Applicant is reminded that upon the cancellation of claims to a none elected invention the none elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

5. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagnew H Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Achutamurthy ponnathapura can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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